K100479

SEP 21 2010

510(k) Summary

ArthroCare® Corporation
Parallax® Contour® Vertebral Augmentation Device

General Information

Submitter Name/Address:	ArthroCare Corporation 680 Vaqueros Avenue Sunnyvale, CA 94085-3523
Establishment Registration Number:	2951580
Contact Person:	Valerie Defiesta-Ng Director, Regulatory Affairs
Contact Phone Number:	408.736.0224
Date Prepared:	February 17, 2010

Device Description

Trade Name:	Parallax® Contour® Vertebral Augmentation Device
Classification Name:	Class II Polymethylmethacrylate (PMMA) bone cement (Section 888.3027) Pro-codes NDN; Class 1 Cement dispenser (Section 888.4200) Pro-codes OAR; and Class I Orthopedic Manual Surgical Instrument (Section 888.4540) Pro-codes HXG

Predicate Devices

Parallax Contour Osteotome	Class 1 exempt
Access Needle Kits	Class I exempt
AVAflex Vertebral Augmentation Needle	K072133

Product Description

The ArthroCare Parallax Contour Vertebral Augmentation Device is used to disrupt cancellous bone and create a void in the vertebral body and fill the void with Parallax Acrylic Resin (bone cement) during kyphoplasty or vertebral augmentation procedures.

Intended Uses

The Parallax Contour Vertebral Augmentation Device when used with the access needle kits are indicated for use during kyphoplasty or vertebral augmentation procedures to create a void in the vertebral body and fill the void with Parallax Acrylic Resin (bone cement). The painful pathological vertebral body compression fractures may result from osteoporosis, benign or malignant lesions such as metastatic cancers and myeloma.

Substantial Equivalence

In establishing substantial equivalence to the predicate device, ArthroCare compared the indications for use, performance specifications, and technology of the subject device to the predicate device. Functional performance testing of the device included torque, insertion and withdrawal, flexure, device attachment/deployment/removal and mechanical displacement of bone have been completed to demonstrate the mechanical characteristics of the device.

A pre-clinical cadaveric study was conducted to evaluate the size void created by the Contour and predicate devices, as well as the volume of Parallax PMMA bone cement delivered during vertebral augmentation. This study demonstrated equivalence in performance of the Contour and predicate devices when used in cadaveric vertebral bodies. In addition, studies were also conducted to characterize Parallax bone cement volume distributed in human cadaver fractured vertebral discs. The test group used the Contour device to create a void prior to vertebral augmentation with bone cement; in the control group the Contour device was not used prior to vertebral augmentation. Comparative data between test group and the control group is reported in terms of relative fill of cement volume per vertebral body volume. Results demonstrates the Contour may be use to successfully create a void in the vertebral body, and that use of Contour device prior to cement augmentation allows significantly more cement delivery into the vertebral body compared to the standard vertebroplasty procedure. Testing was also conducted to compare the performance of the Contour and predicate devices in terms of volume of void created in simulated human foam bone blocks. Based on the results of the study, the void volumes were all similar in size, and no statistically significant differences were noted between the two devices. The pre-clinical studies demonstrate the Contour device performs equivalent to the predicate device.

A clinical study was conducted to evaluate clinical efficacy of the Contour device used in conjunction with PMMA bone cement to fill voids that have been created during percutaneous vertebral augmentation. The outcome showed the volume of the void created in the vertebral body using the Contour ranged from 0.33 to 2.02 cc for individual patients; the volume of PMMA instillation ranged from 2.9 to 8.5 cc; four cases

demonstrated imaging evidence of PMMA extravasation into the paravertebral veins, all four cases were asymptomatic; and after the mean follow-up period, the mean VAS pain score was significantly reduced (dependent t-test, $p<0.01$), where the post-procedure mean score was 2.19 +/- 0.41 points. In all cases, no patient complications were observed. The results of the study demonstrated percutaneous vertebral augmentation using the Contour device was safe and effective for treating symptomatic vertebral compression fractures.

The performance testing, device comparison, pre-clinical, and clinical studies demonstrate that the subject device is substantially equivalent to the predicate device, and is safe and effective.

Summary of Safety and Effectiveness

The Parallax Contour Vertebral Augmentation Device, as described in this premarket notification 510(k), is substantially equivalent to the predicate device. The differences in performance specifications and labeling are not substantial changes or modifications, and do not significantly affect the safety or efficacy of the proposed device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

ArthroCare Corporation
% Ms. Valerie Defiesta-Ng
Director, Regulatory Affairs
680 Vaqueros Avenue
Sunnyvale, California 94085

SEP 21 2010

Re: K100479
Trade/Device Name: ArthroCare® Parallax® Contour® Vertebral Augmentation Device
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: Class II
Product Code: NDN, OAR, HXG
Dated: August 18, 2010
Received: August 19, 2010

Dear Ms. Defiesta-Ng:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

SEP 21 2010

Device Name ArthroCare® Parallax® Contour® Vertebral Augmentation Device

510(k) Number: K 100479

Indications for Use:

The ArthroCare® Parallax® Contour® Vertebral Augmentation Device when used with the access needle kits are indicated for use during kyphoplasty or vertebral augmentation procedures to create a void in the vertebral body and fill the void with Parallax Acrylic Resin (bone cement). The painful pathological vertebral body compression fractures may result from osteoporosis, benign or malignant lesions such as metastatic cancers and myeloma.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use ____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100479